DOCKET NO. ORT1548US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Thomas Schultz et al.

Serial No.: 10/022,138 Art Unit: 1616

Filed : December 13, 2001 Examiner: Sabiha N. Qazi

For : STEROID HORMONE PRODUCTS AND METHODS FOR PREPARING THEM

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Mail Stop Appeal, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

January 27, 2006

(Date)

Joseph S. Kentoffio

Name of applicant, assignee, or Registered Representative

/Joseph S. Kentoffio, Reg. No. 33,189/

(Signature)

January 27, 2006

(Date of Signature)

AUTHORIZATION TO CHARGE DEPOSIT ACCOUNT

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Attached is an Amended Appeal Brief for the above-captioned patent application.

The Commissioner is hereby authorized to charge any fees which may be required in connection with the filing of this Amended Appeal Brief to Account No. 10-0750/ORT1548/JSK. This Authorization is being submitted in triplicate.

Respectfully submitted,

/Joseph S. Kentoffio/
Joseph S. Kentoffio
Attorney for Applicant(s)
Reg. No. 33,189

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3711
DATED: January 27, 2006

Docket No. ORT-1548

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	SCHULTZ, T. et al.
Serial No.	:	10/022,138
Filed	:	December 13, 2001
Title	:	Steroid Hormone Products and Methods for Preparing Them
Art Unit	:	1616
Examiner	:	Qazi, S.

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January 27, 2006
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Joseph S. Kentoffio
(Name of applicant, assignee, or Registered Representative)

/Joseph S. Kentoffio Reg. No. 33,189/
(Signature)

January 27, 2006
(Date of Signature)

ATTENTION: BOARD OF PATENT APPEALS AND INTERFERENCES

APPELLANTS' AMENDED APPEAL BRIEF PURSUANT TO 37 C.F.R. §§ 1.192 and 41.37(D)

Dear Sir:

This Amended Appeal Brief is filed in response to the Notification of Non-Compliant Appeal Brief mailed on January 3, 2006.

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REAL PARTY IN INTEREST

The real party in interest of the above-referenced patent application is Ortho-McNeil Pharmaceutical, Inc., the assignee of record, having a principal place of business at Route 202, Raritan, NJ 08869.

RELATED APPEALS AND INTERFERENCES

A prior appeal was filed in the above-referenced application on January 20, 2004, Appellants having filed a Notice of Appeal on that date. Appellants filed an Appeal Brief in the prior appeal on March 22, 2004. In response to that Appeal Brief, the Examiner mailed a Non-Final Rejection on June 29, 2004, withdrawing the Final Rejection mailed October 21, 2003. A copy of that Non-Final Rejection is already part of the record of this application.

STATUS OF CLAIMS

Claims 1-8 are pending in this application and are the subject of this Appeal. Claims 1-8 stand rejected.

Claims 9-17 were previously withdrawn in view of the restriction requirement issued by the Examiner in the Office Action mailed on March 28, 2003.

STATUS OF AMENDMENTS

The claims stand amended as set forth in the Response To Office Action filed on December 15, 2004.

No claim amendments were filed subsequent to the mailing of the Final Rejection on March 15, 2005.

SUMMARY OF CLAIMED SUBJECT MATTER

Claim 1 is the only independent claim in this application. Claim 1 defines a steroid hormone product having an improved dissolution profile and release rate profile. The product comprises at least one steroid hormone in admixture with a primary excipient. Substantially all of the steroid hormone is in non-crystalline form, and it is stabilized in this form by the excipient. The hormone products taught by the invention are characterized by highly favorable dissolution properties. See, e.g., page 4, lines 16-21 of the specification.

Stabilization of the steroid hormone norgestimate in the high-energy amorphous form by the excipient lactose is described at page 9, line 25 to page 10, line 6 of the specification. The superior dissolution rate of the high-energy amorphous form of the steroid hormone norgestimate, as compared to the lower energy crystalline form, is shown by the data in Table 1 at page 10 of the specification. The improvement in dissolution rate for the amorphous form of steroid hormone norgestimate, subsequent to co-milling with the excipient lactose, as compared to the lower energy crystalline form of norgestimate co-milled with lactose, is shown by the data in Tables 2 and 3 at, respectively, pages 11 and 12 of the specification.

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Whether claims 1-8 are anticipated by US Patent No. 5, 858,405 (Gast), i.e., whether this references discloses each and every aspect of the claimed invention.

Whether claims 1-8 are obvious over US Patent No. 5, 858,405, i.e., whether a person skilled in the art would be lead by the teachings of the Gast reference to the claimed invention.

ARGUMENT

The Rejection Issued Under § 102(b)

Claims 1-8 have been rejected under 35 U.S.C. §§ 102(a) as being anticipated by Gast '405. Gast is not directed to steroid hormone formulations having improved dissolution and release rate properties. Rather, Gast provides a novel tri-phasic regimen for administering oral contraceptives, wherein a combination of an estrogen and a progestin are administered for 23-25 days followed by 3-5 days of estrogen-only administration. Gasts's formulations include a progestin and an estrogen and further include components such as colorants, lubricants, fillers and the excipient lactose. All of these components are well known in the art of formulating oral contraceptives. The novel aspects of Gast are directed to the dosages of the specified hormones and the particular ti-phasic contraceptive regimen taught by Gast.

Gast nowhere teaches a formulation wherein the steroid hormone in the formulation is in non-crystalline form and wherein the hormone is stabilized in this form by the excipient. Instead, and as specifically pointed out by Gast at column 9, line 67 to column 10, line 1, the formulations set forth in his Examples 1 and 2 are prepared by conventional methodology well known to those skilled in the art. The Examiner acknowledges in the Final Office Action that the instant claims differ from Gast in that the instant claims recite non-crystalline steroid hormone, and Gast teaches a crystalline form. Since Gast fails to teach each and every aspect of the claimed steroid hormone products, this reference cannot form the basis of a rejection under 35 U.S.C. § 102(b). MehlBiophile International Corp. v. Milgraum, 52 USPQ 2d 1303, 1306 (Fed. Cir. 1999). Accordingly, appellants request that the Board overturn this rejection.

The Rejection Issued Under § 103(a)

As to the 103(a) rejection, the Examiner argues that the claimed invention would be obvious since no unexpected results and/or criticality of the non-crystalline hormone is shown. Appellants submit the criticality of the steroid hormone in non-crystalline form is clearly set forth in the specification and that, accordingly, the rejection of the claims as obvious over Gast should be withdrawn.

Appellants direct the Board to page 6, lines 15-23, of the specification wherein it is noted that steroid hormones can exist in various solid state forms and that the particular solid state form may significantly affect properties such as dissolution rate and physical/chemical stability. It is further noted in this section of the specification that the higher energy, non-crystalline solid state form will exhibit an increase in dissolution rate over the more stable, lower energy crystalline form. At page 7, line 30 to page 8, line 2, appellants point out that in the manufacture of steroid hormone products it would be highly desirable to increase the dissolution rate of the hormone while at the same time either improving or at least not reducing the physical/chemical stability of the hormone.

These objectives are achieved by the claimed invention. The high-energy amorphous form of the steroid hormone norgestimate is stabilized by the excipient lactose, as described at page 9, line 10 to page 10, line 6. The data in Table 1 demonstrate the difference in dissolution rates for non-crystalline norgestimate as compared to the lower-energy crystalline form. Note that the dissolution rate for amorphous norgestimate at 60 minutes is about the same as the lower energy crystalline form at 120 minutes and that the dissolution rate for the amorphous form at 120 minutes is significantly higher than the rate for the crystalline form at 140 minutes. The data in Tables 2 and 3 illustrates the effect on

dissolution rate as norgestimate begins to re-crystallize from the higher energy amorphous form. As shown by these data, the dissolution rate of norgestimate decreases as the steroid converts to the lower energy crystalline form. The data in Table 4 show that the dissolution properties of norgestimate are not only dependent on storage conditions, but also on the mixing energetics imparted during the manufacturing process. Note that as energy is imparted over time and higher levels of amorphous norgestimate are present, the dissolution characteristics improve even when storage is unprotected under accelerated conditions.

As stated in the specification at page 13, lines 11-22, taken together the data from these studies demonstrate that when a mixture of an excipient and a steroid hormone is subjected to sufficient mechanical energy, the excipient and the steroid active ingredient form a less crystalline, more highly energetic composition. Furthermore, under appropriate mixing conditions, the lactose component stabilizes the steroid in a highly energetic, substantially non-crystalline state, thus preventing recrystallization of the steroid. The highly energetic, non-crystalline steroid active ingredient dissolves more readily and is better able to maintain desirable dissolution characteristics under a variety of conditions of ambient humidity and ambient temperature.

The portions of the specification cited above establish the criticality of the non-crystalline steroid hormone and the unexpected results that derive from this form of hormone. Where, as here, the specification contains specific data indicating substantially improved properties, unexpected results are established, absent evidence to the contrary. In re Soni, 34 USPQ 2d 1684, 1687-88 (Fed. Cir. 1995).

In view of the foregoing, Appellants request that the Examiner's Final Rejection be overturned and that this application be passed to allowance at the earliest possible date.

Respectfully submitted,

By: /Joseph S. Kentoffio/

Joseph S. Kentoffio
Reg. No. 33,189

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-3711
Dated: January 27, 2006

CLAIMS APPENDIX

1. A steroid hormone product having improved dissolution and release rate properties, said product comprising at least one steroid hormone in admixture with an excipient, wherein substantially all of said at least one steroid hormone is in non-crystalline form and wherein said excipient stabilizes said hormone in its non-crystalline form.

2. The steroid hormone product of claim 1, wherein the primary excipient is selected from the group consisting of dextrose, fructose, sorbitol, xylitol, sucrose, lactose, mannitol, dextrate, cellulose, starch and mixtures thereof.

3. The steroid hormone product of claim 1 wherein the steroid hormone is at least one of a progestin and an estrogen

4. The steroid hormone product of claim 3, wherein the steroid hormone is a progestin selected from the group consisting of norgestimate, norgestrel, levonorgestrel, norethindrone and desogestrel.

5. The steroid hormone product of claim 4 wherein the steroid hormone is norgestimate and the excipient is lactose.

6. The steroid hormone product of claim 3, wherein the product is one of an oral contraceptive product and a hormone replacement therapy product.

CLAIMS APPENDIX CON'T

7. The steroid hormone product of claim 6, wherein the product is an oral contraceptive product comprising from about 10 μg to about 50 ug of an estrogen and/or from about 50 μg to about 300 μg of a progestin.

8. The steroid hormone product of claim 7, wherein the progestin is norgestimate and the excipient is lactose.

EVIDENCE APPENDIX

None

RELATED PROCEEDINGS APPENDIX

None